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FILED
U.S. DISTRICT COURT

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DISTRICT OF UTAH

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA,	:	INDICTMENT
Plaintiff,	:	
vs.	:	VIO. 18 U.S.C. § 1341, MAIL FRAUD;
	:	21 U.S.C. §§ 333(t) and 353(e)(2)(A)
	:	and (B)(1)(D); UNLICENSED
MICHAEL LAWRENCE O'DONNELL	:	WHOLESALE DISTRIBUTION OF
Defendant.	:	PRESCRIPTION DRUGS.

Case: 2:11-cr-00556
Assigned To : Waddoups, Clark
Assign. Date : 7/5/2011
Description: USA v.

The Grand Jury charges that:

GENERAL ALLEGATIONS

At all times material to this indictment:

The Authorities

1. The United States Food and Drug Administration ("FDA") enforced the provisions of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), Title 21, United States Code, Sections 301-399, and the regulations promulgated thereunder. The FDA regulated drugs distributed in interstate commerce, including activities related to drug manufacturing and labeling.

2. The FDCA defined a "drug" as including (a) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; (b) articles (other than food) intended to affect the structure or any function of the human body; and (c) articles intended for use as components of drugs. 21 U.S.C. § 321(g)(1).

3. The Public Health Service Act defined a "biological product" as including a toxin, therapeutic serum, blood, or blood component or derivative applicable to the prevention, treatment, or cure of a disease or condition in human beings. 42 U.S.C. § 262(i). When a "biological product" met the definition of a "drug," as stated in paragraph 2 of this Indictment, the "biological product" also constituted a "drug" under the provisions of 21 U.S.C. § 321(g).

4. A drug constituted a "new drug" if it were "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof" 21 U.S.C. § 321(p)(1). To be lawfully introduced into interstate commerce for marketing, new drugs required an approved marketing application. 21 U.S.C. §§ 331(d) and 355. "Approved marketing applications" included new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs"). 21 U.S.C. § 355. An approved NDA or ANDA conferred authority on the sponsor of the NDA or ANDA to manufacture and distribute the drug at issue and required, among other things, that the drug be manufactured only at facilities authorized under the approved NDA or ANDA and that the drug bear only approved labeling. 21 U.S.C. § 355. Approved NDAs and ANDAs permitted distribution of drugs only for uses prescribed, recommended or suggested in the approved labeling.

5. A biological product classified as a “new drug” did not require an approved NDA or ANDA if it was the subject of an FDA-approved Biologics License Application (“BLA”). 42 U.S.C. § 262(j).

6. NDAs, ANDAs, and BLAs described in great detail how the product worked, how it was manufactured, and how it was labeled. The application process required FDA to approve the manufacturing, labeling, and packaging set forth in the application. 21 U.S.C. § 355(b)(1); 42 U.S.C. § 262(a). The approval process addressed the chemical composition of the product, the safety and effectiveness the product, and elements of the distribution of the product, such as the methods used in, and the facilities and controls used for, the product's manufacturing, processing, packing, and the proposed labeling. 21 U.S.C. § 355(b)(1)(A)-(F); 42 U.S.C. § 262(a)(2)(C). The approval process was specific to each manufacturer and each product. 21 C.F.R. §§ 314.50 and 601.2. The approval process required, among other things, that a manufacturer provide the proposed text of the labeling for the product. 21 C.F.R. §§ 314.50(c) and 601.2(a). Approval granted to a particular manufacturer for a particular product to be distributed in the United States did not constitute approval of a drug or biological product with labeling that differed from the labeling in the FDA-approved application – even one with the same chemical composition – to be imported into and distributed in the United States.

7. As a subset of drugs governed by the FDCA, the FDA also regulated “prescription drugs.” FDCA defined “prescription drugs” as including those drugs which – because of their toxicity or other potential harmful effects, or the methods of their use, or the collateral measures necessary to their use – were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which were required to be administered under the

professional supervision of a practitioner licensed by law to administer such drugs as a condition of the FDA for approving such drugs. 21 U.S.C. § 353(b)(1).

8. Prescription drug manufacturers generally distributed their products to doctors, pharmacies, and hospitals through licensed wholesale distributors.

9. A prescription drug may have been purchased and distributed by several licensed wholesale distributors before it was delivered to a doctor, pharmacy, or hospital.

10. Some wholesale distributors obtained prescription drugs from questionable, and often unlicensed, sources that sell the drug for prices significantly below the average wholesale price of the drug. Those sources may have purchased stolen, counterfeit, sub-potent, unapproved, expired, or otherwise unlawful drugs.

11. To prevent the distribution of stolen, counterfeit, sub-potent, unapproved, expired, or otherwise unlawful drugs, Congress enacted the Prescription Drug Marketing Act ("PDMA"), which it incorporated into the FDCA.

12. Under the PDMA, no person could engage in the wholesale distribution in interstate commerce of prescription drugs in a particular state unless such person first obtained a license to do so from that State. 21 U.S.C. § 353(e)(2)(A) and 21 C.F.R. § 205.4.

13. The PDMA defined "wholesale distribution" as the distribution of drugs to other than the consumer or patient. 21 U.S.C. § 353(e)(3)(B). The act further defined "state" as any State or Territory of the United States, the District of Columbia and the Commonwealth of Puerto Rico. 21 U.S.C. § 321(1)(1).

14. The statute specifically precluded a person to engage in or cause another person to engage in the distribution of drugs in violation of 21 U.S.C. § 353(e). 21 U.S.C. § 331(t). It

further precluded introduction into interstate commerce of any unapproved new drugs. 21 U.S.C. § 331(d).

The Defendant

15. The defendant, MICHAEL LAWRENCE O'DONNELL, was a citizen and resident of the United States. The defendant owned and operated several businesses known as the GLOBAL group of companies which acted as one. The companies operated under the names of GLOBAL USA, GLOBAL GROUP, CCP, GLOBAL RX SOURCING, LLC, GMD INTERNATIONAL, INC. ESC, GHRX, GLOBAL PHARMACY, and others. All of these businesses described and held themselves out as medicine wholesalers. As part of his business, the defendant secured wholesale quantities of prescription pharmaceutical drugs from his related company, GHRX, located in the United Kingdom. GHRX obtained these pharmaceuticals from unknown sources throughout the world. The defendant tasked his employee(s) to ship pharmaceutical drugs obtained from GHRX to health care providers throughout the United States.

The Drugs

16. In December of 1991, the FDA approved an application for Botox®, the brand name of a prescription drug derived from Botulinum Toxin Type A and manufactured by Allergan, Inc., for the treatment of cervical dystonia in adults. Botulinum Toxin Type A is a highly potent and potentially dangerous toxin, and can cause the disease botulism when present in human beings in a sufficient amount. Botulism is a muscle-paralyzing condition in which Botulinum Toxin Type A binds to nerve endings at the point where nerves join muscles, preventing the nerves from signaling the muscles to contract. Botulism can result in weakness

and paralysis that severely affects, among other things, the muscles that control breathing. Severe botulism generally results in death, unless the patient receives proper care to ensure continued breathing. Recovery occurs only when the affected nerves grow new endings, a process that can extend over several months, although recovery time varies greatly from case to case.

17. In April of 2002, FDA approved a supplemental application to Allergan's original Botox application. The supplemental application related to the treatment of glabellar lines, commonly referred to as wrinkles. Under this FDA approval, Allergan's Botulinum Toxin Type A product constituted a prescription drug marketed and labeled for this supplemental usage as "Botox® Cosmetic."

18. On September 17, 2001, FDA approved the application for Aranesp, the brand name of a prescription drug manufactured by Amgen, for the treatment of anemia associated with renal failure and for anemia resulting from chemotherapy.

19. On May 15, 1996, FDA approved the application for Gemzar, a prescription drug manufactured by Eli Lilly, for the treatment of breast cancer, non-small cell lung cancer, and pancreatic cancer.

20. On August 20, 2001, FDA approved the application for Zometa, the brand name of a prescription drug manufactured by Novartis, for the treatment of cancer.

THE SCHEME AND ARTIFICE TO DEFRAUD

21. From on or about October 2005 and continuing until on or about March 2007, the exact dates being unknown to the Grand Jury, in the District of Utah, and elsewhere, the defendant,

MICHAEL LAWRENCE O'DONNELL,

knowingly devised and intended to devise a scheme and artifice to defraud. The purpose of the scheme and artifice was to defraud health care providers, end-user patients, government programs, and private insurers. For the purpose of executing such scheme and artifice, and attempting to do so, the defendant knowingly deposited and caused to be deposited with commercial interstate carriers items to be sent and delivered by the carriers, and knowingly caused items to be delivered by commercial interstate carriers, according to the direction thereon. The items, so deposited, sent, and delivered, were diverted prescription drugs which the defendant knew lacked FDA approval.

It was part of the artifice and scheme to defraud that:

22. Defendant, MICHAEL LAWRENCE O'DONNELL, received orders for prescription pharmaceutical drugs, including Botox, Aranesp, Gemzar, and Zometa, that had been placed with and through CLINICAL CARE PHARMACY (CCP) and CONCORD DRUG STORE (CONCORD), internet web sites that held themselves out to be and functioned as internet-based pharmacies (hereafter, "internet pharmacy web sites").

23. The internet pharmacy web sites represented that their prices were competitive or lower than prices for comparable drugs available through other pharmacies and further represented, among other things, that their products were approved by United States and

Canadian regulators and that their purported brand-name and generic prescription pharmaceutical drugs were equivalent to, or exceeded, North American pharmacy standards.

24. Contrary to the foregoing representations, the prescription pharmaceutical drugs offered through these internet pharmacy web sites were not, in fact, approved by the FDA for introduction and use in the United States.

25. It was a further part of the manner and means of the scheme that the defendant, MICHAEL LAWRENCE O'DONNELL, received the order-information from the internet pharmacy web sites either directly from the web-site operator through an email communication or by accessing a private web site that housed an inventory of orders taken in from the internet pharmacy web sites. The order information consisted of the names of the customers (health care practitioners), their mailing addresses, and the type and amount of the drugs ordered.

26. The defendant received foreign, unapproved drugs in Utah from GHRX in the United Kingdom. The defendant filled orders by placing the foreign, unapproved drugs inside nondescript boxes and caused these boxes to be shipped and delivered to health care practitioners using FedEx services. The defendant instructed that the FedEx boxes contain a false return address, so as to conceal the actual originating shipping location.

27. At all relevant times, the defendant shipped prescription drugs from Utah, but the defendant was not licensed by the State of Utah to engage in the wholesale distribution of prescription drugs.

28. Upon mailing out the packages containing the prescription pharmaceutical drugs, the defendant sent the web site operator, through emails, lists of tracking numbers for the packages that he sent, as proof that the orders had been filled. In return, the web site operator

paid the defendant for shipping the orders by arranging for bank wire transfers to be made to bank accounts that the defendant maintained in the United Kingdom for his business.

29. The defendant's efforts to obtain foreign, unapproved, and diverted prescription drugs from the United Kingdom and further distribute them from Utah to health care practitioners throughout the United States defrauded the health care practitioners who purchased and administered the drugs, the end-user patients who were administered the drugs, and the government and private insurance companies who reimbursed the health care practitioners for the drugs, which were not what they purported to be – that is, drugs properly distributed under federal law that met or exceeded North American pharmacy standards.

COUNTS 1 THROUGH 12

18 U.S.C. § 1341

(Mail Fraud)

30. The Grand Jury incorporates and realleges the allegations contained in paragraphs 1 through 29 above.

31. On or about each of the dates identified below, in the Central Division of the District of Utah,

MICHAEL LAWRENCE O'DONNELL,

defendant herein, for the purpose of executing the above-described scheme and artifice to defraud, and attempting to do so, knowingly deposited and caused to be deposited with commercial interstate carriers, items to be sent and delivered by the carriers, and knowingly caused items to be delivered by commercial interstate carriers, according to the directions thereon. As the defendant well knew, the items, so deposited, sent, and delivered, were diverted

prescription drugs from an unlicensed wholesale distributor and such drugs were not approved by the FDA:

Count	"On or About" Date	Unapproved Prescription Drug	Shipped From:	FedEx Tracking Number	Shipped To Health Care Provider In:
1	July 5, 2006	Botox	Utah	790979565989	New York
2	July 12, 2006	Zometa	Utah	791994003940	Texas
3	July 26, 2006	Botox	Utah	792163161528	Texas
4	August 23, 2006	Botox	Utah	792188339238	Pennsylvania
5	September 19, 2006	Botox	Utah	791125999022	Wisconsin
6	October 3, 2006	Gemzar	Utah	790576039050	Illinois
7	October 31, 2006	Botox	Utah	799028669658	Wisconsin
8	November 6, 2006	Botox	Utah	792878856184	North Carolina
9	December 13, 2006	Botox	Utah	798564144027	Colorado
10	January 15, 2007	Botox	Utah	799068342040	Florida
11	February 6, 2007	Botox	Utah	799582735918	North Carolina
12	February 28, 2007	Botox	Utah	791238604277	California

All in violation of 18 U.S.C. § 1341.

COUNTS 13 THROUGH 25

**21 U.S.C. §§ 331(t), 353(e)(2)(A), and 333(b)(1)(D)
(Unlicensed Wholesale Distribution)**

32. Paragraphs 1 through 31 of the Indictment are realleged and incorporated by reference as though fully set herein.

33. On or about the dates listed below, in the Central Division of the District of Utah,

MICHAEL LAWRENCE O'DONNELL,

defendant herein, knowingly did and caused, through Global Pharmacy in Utah, the wholesale distribution of prescription drugs from Utah to health care practitioners outside of Utah in violation of Title 21, United States Code 353(e)(2)(A), in that defendant was not licensed by the State of Utah to engage in the wholesale distribution of prescription drugs:

Count	"On or About" Date	Prescription Drug	Shipped From:	FedEx Tracking Number	Shipped To Health Care Provider In:
13	July 5, 2006	Botox	Utah	790979565989	New York
14	July 10, 2006	Aranesp	Utah	790984479488	Ohio
15	July 12, 2006	Zometa	Utah	791994003940	Texas
16	July 26, 2006	Botox	Utah	792163161528	Texas
17	August 23, 2006	Botox	Utah	792188339238	Pennsylvania
18	September 19, 2006	Botox	Utah	791125999022	Wisconsin
19	October 3, 2006	Gemzar	Utah	790576039050	Illinois
20	October 31, 2006	Botox	Utah	799028669658	Wisconsin
21	November 6, 2006	Botox	Utah	792878856184	North Carolina
22	December 13, 2006	Botox	Utah	798564144027	Colorado
23	January 15, 2007	Botox	Utah	799068342040	Florida
24	February 6, 2007	Botox	Utah	799582735918	North Carolina
25	February 28, 2007	Botox	Utah	791238604277	California

All in violation of 21 U.S.C. §§ 331(t), 353(e)(2)(A), and 333(b)(1)(D).

A TRUE BILL:

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FOREPERSON OF THE GRAND JURY

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